ELSEVIER

The Spine Journal 14 (2014) 65–72

THE SPINE JOURNAL

Clinical Study

Mild diabetes is not a contraindication for surgical decompression in cervical spondylotic myelopathy: results of the AOSpine North America multicenter prospective study (CSM)

Paul M. Arnold, MD[a,*], Michael G. Fehlings, MD, PhD[b,c], Branko Kopjar, MD, PhD[d], Sangwook Tim Yoon, MD[e], Eric M. Massicotte, MD[b,c], Alexander R. Vaccaro, MD, PhD[f], Darrel S. Brodke, MD[g], Christopher I. Shaffrey, MD[h], Justin S. Smith, MD, PhD[h], Eric J. Woodard, MD[i], Robert J. Banco, MD[j], Jens R. Chapman, MD[k], Michael E. Janssen, DO[l], Christopher M. Bono, MD[m], Rick C. Sasso, MD[n], Mark B. Dekutoski, MD[o], Ziya L. Gokaslan, MD[p]

[a]*Department of Neurosurgery, University of Kansas Medical Center, 3901 Rainbow Blvd., Mail Stop 3021, Kansas City, KS 66160, USA*
[b]*Division of Neurosurgery, University of Toronto, Toronto, Ontario, Canada*
[c]*Toronto Western Hospital, 399 Bathurst St, #4W-449, Toronto, ON, Canada*
[d]*Department of Health Services, University of Washington, Box 359455, 4333 Brooklyn Ave NE, Rm 14-315, Seattle, WA 98195-9455, USA*
[e]*Department of Orthopaedic Surgery, Emory University, Emory Orthopaedics & Spine Center, 59 Executive Park South, Atlanta, GA 30329, USA*
[f]*Department of Orthopaedic Surgery, Thomas Jefferson University, Rothman Institute, 925 Chestnut St, 5th Floor, Philadelphia, PA 19107-4216, USA*
[g]*Department of Orthopaedics, University of Utah, University Orthopaedic Center, 590 Wakara Way, Salt Lake City, UT 84108, USA*
[h]*Department of Neurological Surgery, University of Virginia Health System, PO Box 800212, Charlottesville, VA 22908-0212, USA*
[i]*Department of Orthopedic Surgery, New England Baptist Hospital, 125 Parker Hill Ave, Boston, MA 02120, USA*
[j]*Boston Spine Group, 299 Washington St, Newton, MA 02458, USA*
[k]*Department of Orthopaedics, University of Washington, Orthopaedic Trauma Surgery Clinic at Harborview, Harborview Medical Center, 1 West Clinic, Box 359798, 325 Ninth Ave, Seattle, WA 98104, USA*
[l]*Spine Education and Research Institute, Center for Spinal Disorders, 9005 Grant St., Suite 200, Thornton, CO 80229, USA*
[m]*Department of Orthopaedic Surgery, Brigham and Women's Hospital, 75 Francis St., Boston, MA 02115, USA*
[n]*Department of Orthopedic Surgery, Indiana Spine Group, 8040 Clearvista Parkway, Suite 450, Indianapolis, IN 46256, USA*
[o]*The CORE Institute, Center for Orthopedic Research and Education, 3010 W. Agua Fria Fwy #100, Phoenix, AZ 85027, USA*
[p]*Department of Neurosurgery, Johns Hopkins University School of Medicine, Meyer 7-109, 600 North Wolfe St., Baltimore, MD 21287, USA*

Received 12 April 2012; revised 8 March 2013; accepted 1 June 2013

Abstract

BACKGROUND CONTEXT: Cervical spondylotic myelopathy (CSM) is a chronic spinal cord disease and can lead to progressive or stepwise neurologic decline. Several factors may influence this process, including extent of spinal cord compression, duration of symptoms, and medical co-morbidities. Diabetes is a systemic disease that can impact multiple organ systems, including the central and peripheral nervous systems. There has been little information regarding the effect of diabetes on patients with coexistent CSM.

PURPOSE: To provide empirical data regarding the effect of diabetes on treatment outcomes in patients who underwent surgical decompression for coexistent CSM.

STUDY DESIGN/SETTING: Large prospective multicenter cohort study of patients with and without diabetes who underwent decompressive surgery for CSM.

PATIENT SAMPLE: Two hundred thirty-six patients without and 42 patients with diabetes were enrolled. Of these, 37 were mild cases and five were moderate cases. Four required insulin. There were no severe cases associated with end-organ damage.

OUTCOME MEASURES: Self-report measures include Neck Disability Index and version 2 of 36-Item Short Form Health Survey (SF-36v2), and functional measures include modified Japanese Orthopedic Association (mJOA) score and Nurick grade.

FDA device/drug status: Not applicable.

Author disclosures: Listed at the end of this article.

* Corresponding author. Department of Neurosurgery, University of Kansas Medical Center, 3901 Rainbow Blvd., Mail Stop 3021, Kansas City, KS 66160, USA. Tel.: (913) 588-7587; fax: (913) 588-7596.

E-mail address: parnold@kumc.edu (P.M. Arnold)

http://dx.doi.org/10.1016/j.spinee.2013.06.016

METHODS: We compared presurgery symptoms and treatment outcomes between patients with and without diabetes using univariate and multivariate models, adjusting for demographics and comorbidities.

RESULTS: Diabetic patients were older, less likely to smoke, and more likely to be on social security disability insurance. Patients with diabetes presented with a worse Nurick grade, but there were no differences in mJOA and SF-36v2 at presentation. Overall, there was a significant improvement in all outcome parameters at 12 and 24 months. There was no difference in the level of improvement between the patients with and without diabetes, except in the SF-36v2 Physical Functioning, in which diabetic patients experienced significantly less improvement. There were no differences in surgical complication rates between diabetic patients and nondiabetic patients.

CONCLUSIONS: Except for a worse Nurick grade, diabetes does not seem to affect severity of symptoms at presentation for surgery. More importantly, with the exception of the SF-36v2 Physical Functioning scores, outcomes of surgical treatment are similar in patients with diabetes and without diabetes. Surgical decompression is effective and should be offered to patients with diabetes who have symptomatic CSM and are appropriate surgical candidates.

Keywords: Cervical spondylotic myelopathy; Diabetes; Surgical treatment; Functional outcomes; Quality of life

Introduction

Cervical spondylotic myelopathy (CSM) is a progressive degenerative disease that results in compression of the cervical spinal cord or nerve roots, leading to neurologic dysfunction [1,2]. Diabetes mellitus is a chronic systemic disease characterized with high levels of glucose in blood. Patients with diabetes may develop multiple neurologic sequelae, mainly associated with macrocirculatory and microcirculatory complications.

There have been only few studies that have analyzed the relationship between diabetes and CSM [3–8]. These studies were small, retrospective in nature, reported data from a single center, and focused only on neurologic outcomes, while failing to report on more important patient-relevant quality-of-life outcomes. These studies do, however, suggest an adverse impact of diabetes on neurologic outcomes.

As a result of these uncertainties, we analyzed data from a large, prospective, multicenter study and compared clinical- and patient-reported outcomes of surgical decompression in CSM patients with and without diabetes.

Methods

This study was approved by the internal review boards at all participating sites and the internal review board overseeing the Data Management Center. This study is registered with clinicaltrials.gov number NCT00285337 (Figure).

Subjects

Three hundred two patients with clinically and radiographically confirmed CSM were enrolled in a multicenter prospective study at 11 sites in the United States and one site in Canada between December 2005 and September 2007. Available for analysis were 278 patients, 42 of whom had diabetes and 236 of whom did not have diabetes at baseline. The key inclusion criteria were age 18 years and older, symptomatic CSM with clinical signs of myelopathy, objective evidence of cervical cord compression as determined by magnetic resonance imaging, no prior surgical treatment for myelopathy, and an absence of symptomatic lumbar stenosis. There were no restrictions on the duration of symptoms or prior nonsurgical treatment. Subjects were treated by either an anterior or a posterior decompressive/reconstructive approach at the discretion of the operating surgeon. Postoperative rehabilitation was per standard of care at the treating institution.

One subject from a nondiabetic cohort died within 24 months after surgery of an unrelated cause. A total of 23 subjects (6 from diabetic cohort and 17 from nondiabetic cohort) withdrew from the study before the 24-month follow-up. At 12 months, follow-up data were available for 87.4% of eligible subjects in a nondiabetic group and 84.2% in the diabetic group. At 24 months, follow-up data were available for 76.1% subjects in the nondiabetic group and 72.2% in the diabetic group.

Outcomes data

Outcome evaluations were performed at preplanned study follow-ups at 6, 12, and 24 months after the surgery. Outcome evaluations included the modified Japanese Orthopedic Association (mJOA) score [9], the Nurick grade [1,10], the Neck Disability Index (NDI) [11], the version 2 of 36-Item Short Form Health Survey (SF-36v2) [12], and an assessment of treatment complications. The mJOA score and Nurick grade are clinician administered and measure the severity of neurologic impairment. The mJOA evaluates four clinical dimensions: motor dysfunction score for upper and lower extremities, sensation loss, and sphincter dysfunction. The total score ranges from 0 (worst) to 18 (best). The Nurick grade is a simple measure of neurologic dysfunction and ranges from 0 (best) to 6 (worst). The NDI

is a self-report that evaluates functional outcomes related to neck conditions and ranges from 0 (best) to 100 (worst). The SF-36v2 is a widely used measure of patient-reported generic health status that describes health status across eight global dimensions: Physical Functioning; Pain; Role Limitation—Physical; Emotional Well-Being; Role Limitation—Emotional; Social Functioning; Energy/Fatigue; and Global Health. The eight global dimensions can also be summarized in two composite scores: the SF-36v2 Physical Component Score and the Mental Composite Score. The composite scores were calculated using the 1998 US norms and the orthogonal approach to transformation.

Complications were prospectively followed using a predetermined list of 30 anticipated complications associated with the surgical treatment of CSM, and complications not on the list were recorded. The entire list of complications was prospectively evaluated by participating investigators at postsurgery, 6, 12, and 24 months, as well as at all unplanned visits. More than 300 adverse events have been reported. Reported events data were adjudicated by an adverse event committee composed of a group of physicians not participating in the study. Adverse events were categorized as treatment complications and treatment-unrelated events.

Analytical methods

One subject was missing values for baseline mJOA score and Nurick grade; these were imputed using regression imputation. Missing follow-up scores for subjects who failed to attend their follow-up visits were assumed to be missing at random and were imputed using the multiple imputation method [13,14]. Multiple imputation was performed using SAS/STAT PROC MI with the Markov chain model, full imputation, and multiple chains. Ten imputed samples were created.

Subjects were divided into two groups based on the presence of diabetes at baseline. The information about the presence and severity of diabetes was based on a preplanned prospective data collection at baseline investigation, which specifically asked about the presence of diabetes at enrollment. Furthermore, we cross-checked the medications list to identify any subjects on glucose-lowering medications or insulin.

The analysis of differences between the groups in preoperative and operative characteristics was analyzed by *t* test for the continuous variables and chi-square tests for categorical variables. Testing of statistical significance of changes in outcome variables at 6, 12, and 24 months was performed by analysis of variance (ANOVA) for repeated measurement on the imputed sample. In the case of overall statistical significance, this analysis was followed by a series of contrast-type models investigating changes between 6, 12, and 24 months. The testing of statistical differences within and between the groups with and without diabetes was performed by the two-way repeated measurement ANOVA. Three factors were analyzed in two-way repeated measurement ANOVA; *Time* (repeated factor) with the levels of "baseline," "12 months," and "24 months"; *Diabetes* (independent factor) with the levels of "present" and "absent," and *time*×*diabetes* interaction. The common inferences from the statistics obtained from the 10 imputed samples were estimated using SAS/STAT PROC MIANALYZE [15]. Two

EVIDENCE & METHODS

Context
Diabetes can diminish neurological improvement after decompressive spinal surgery. The authors aimed to assess whether this was the case for CSM surgeries.

Contribution
Comparing cohorts with and without diabetes they found minimal differences both in regards to presentation and surgical outcomes.

Implications
The findings are interesting, especially in an era of bundled payments in which surgeons may be deterred from performing surgery on higher risk patients. It is also important to note that, as the title suggests, these patients had *mild* diabetes. The conclusions may not apply to patients with more significant disease.

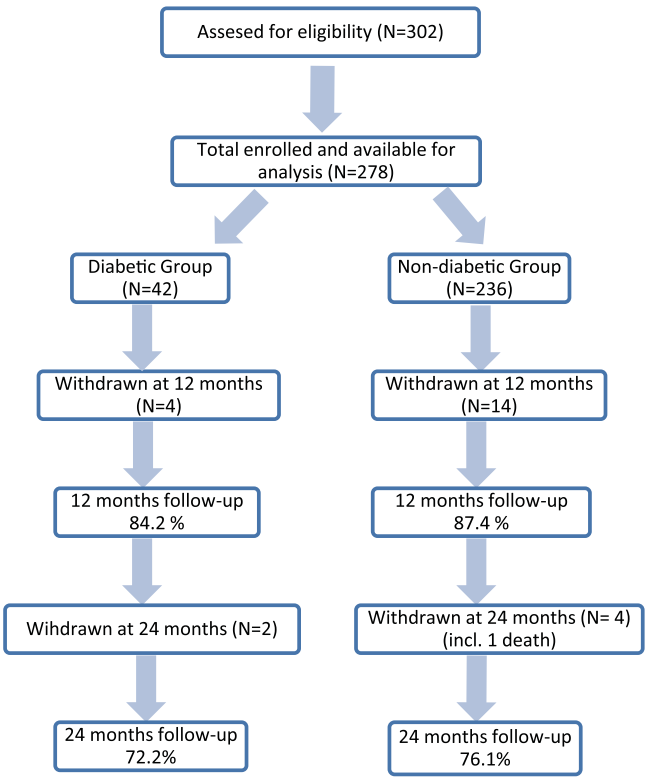

Figure. STROBE flow diagram. STROBE, Strengthening the Reporting of Observational Studies in Epidemiology.

Table 1
Baseline demographics by diabetes status

Variable	Not diabetic (N=236)	Diabetic (N=42)	p Value
Age (y)	55.66 (11.76)	60.12 (10.75)	.0176
Sex (female, %)	40.25	42.86	.8648
Current smoker, %	27.97	14.29	.0840
Body mass index, %			.0072
<18.5	1.72	0.00	
18.5–25	26.61	7.14	
25–30	40.34	38.10	
30 or more	31.33	54.76	
Race, %			.0515
White	84.75	69.05	
Native Hawaiian/Pacific Islander	0.42	0.00	
African American	7.63	23.81	
American Indian/Alaska Native	0.42	0.00	
Asian	3.39	2.38	
Other	3.39	4.76	
Comorbidities, %			
Cardiovascular	41.53	73.81	.0001
Respiratory	11.86	23.81	.0499
Gastrointestinal	17.37	16.33	.8264
Renal	4.24	4.76	.6996
Psychiatric	21.61	35.71	.0745
Rheumatologic	7.63	14.29	.2265
Neurologic	7.20	21.43	.0077
Receiving social security	36.02	52.38	.0578
Stenosis source, %			
Spondylosis	77.97	80.95	.8389
Disc	72.03	59.52	.1420
OPLL	8.47	9.52	.7687
Hypertrophied ligamentum flavum	24.58	11.90	.0748
Congenital stenosis	15.68	14.29	1.0000
Subluxation	5.08	2.38	.6990
Type of surgery, %			.8443
Anterior surgery	61.44	51.14	
Posterior surgery	33.47	38.10	
Circumferential	5.08	4.76	
Duration of symptoms (mo)	24.19 (37.33)	34.64 (76.67)	.3915
Number of levels operated on	3.81 (1.26)	4.14 (1.28)	.1242

OPLL, ossification of the posterior longitudinal ligament.

sets of analysis were performed on all outcomes in the two-way repeated ANOVA, unadjusted and adjusted. The adjusted analysis reduces dissimilarities in patient baseline characteristics between the groups, adjusting for possible effect of confounding because of dissimilarities in baseline characteristics. The selection of baseline characteristics to be used in adjustment was performed based on a series of multiple regression models. All statistical analyses were performed using SAS/STAT, version 9.3 (SAS Institute, Inc., Cary, NC, USA).

Results

There were 42 (15.1%) subjects with diabetes in the study. Of these, 37 (88%) had mild diabetes that was controlled with oral agents or diet only, and 5 (12%) had moderately severe disease that was poorly controlled by oral agents (one subject) or required use of insulin (four subjects). No subjects required hospitalization for diabetes in the last 6 months or had diabetes associated with end-organ failure. The key demographic, clinical, and outcomes baseline parameters for the study groups are summarized in Tables 1 and 2. Subjects with and without diabetes differed in several baseline characteristics. Subjects with diabetes were older; had higher body mass index; were more likely to be African American; and were more likely to have cardiovascular, respiratory, psychiatric, and neurologic comorbidities ($p<.05$). They also had worse preoperative Nurick grade (3.40 and 3.03 in the diabetic and nondiabetic groups, respectively, $p<.05$). There was a trend toward lower level of mJOA in the diabetes group (12.93 and 12.24, respectively), although this difference was not statistically significant ($p=.0896$). There were no significant differences in preoperative NDI and SF-36v2 between the groups (Table 2).

Table 2
Baseline neurologic, functional, and SF-36v2 health profile by diabetes status (N=278)

Variable	Not diabetic (N=236)	Diabetic (N=42)	p Value
NDI	41.52 (20.51)	43.13 (22.59)	.6804
mJOA	12.93 (2.78)	12.24 (2.31)	.0896
Nurick	3.09 (0.98)	3.40 (0.89)	.0403
SF-36v2			
Physical Functioning	5.79 (11.6)	1.70 (9.64)	.0571
Social Functioning	36.32 (13.13)	38.81 (13.94)	.3051
Role Limitation—Physical	31.44 (12.01)	30.98 (10.60)	.8060
Role Limitation—Emotional	36.34 (15.53)	37.34 (16.53)	.7284
Bodily Pain	35.62 (10.69)	37.61 (11.76)	.3278
General Health	44.08 (11.05)	42.71 (9.31)	.4132
Emotional Well-Being	40.46 (13.38)	43.22 (14.15)	.2619
Energy/Fatigue	40.91 (11.70)	41.60 (12.66)	.7518
Physical Health Factor	36.22 (9.63)	36.50 (9.73)	.8714
Mental Health Factor	39.81 (10.80)	41.34 (11.16)	.4308

NDI, Neck Disability Index; mJOA, modified Japanese Orthopedic Association; SF-36v2, version 2 of 36-Item Short Form Health Survey.

Changes in the outcome measures between baseline, 12 months, and 24 months by group are shown in Table 3. Overall, mJOA, NDI, and Nurick grade have improved significantly, from baseline to 12 and 24 months. Also, Role Limitation—Physical, Bodily Pain, and Physical Component Score SF-36v2 dimensions improved. At 12 and 24 months, patients with diabetes experienced significantly less improvement in SF-36v2 Physical Functioning than those without diabetes ($p<.05$ for the time×diabetes factor) (Table 3).

Changes in the outcome measures between baseline and 12- and 24-month follow-up, adjusted for baseline confounders, are summarized in Table 4. The results after the adjustment remained the same compared with the findings before the adjustment. The difference in the extent of improvement in SF-36v2 Physical Functioning remained statistically significantly lower in patients with diabetes than those without diabetes ($p<.05$).

Table 3
Changes in outcome parameters between diabetic and nondiabetic patients receiving decompression surgery for cervical spondylotic myelopathy (N=255)

	Control			Diabetes					
Variable	Baseline	12 mo	24 mo	Baseline	12 mo	24 mo	Diabetes	Time	Time×diabetes
mJOA	13.0 (0.2)	15.8 (0.2)	16.1 (0.2)	12.1 (0.4)	15.2 (0.4)	15.8 (0.5)	.05	<.001	NS
Nurick	4.1 (0.1)	2.5 (0.1)	2.4 (0.1)	4.4 (0.2)	2.7 (0.2)	2.6 (0.3)	NS	<.001	NS
NDI	41.5 (1.5)	30.0 (1.5)	30.1 (1.6)	45.2 (3.6)	34.9 (4.0)	36.8 (4.2)	NS	<.010	NS
SF-36v2									
Physical Functioning	33.0 (0.9)	39.5 (0.9)	38.3 (0.9)	30.6 (2.1)	33.3 (2.3)	31.1 (2.2)	NS	NS	.003
Role Limitation—Physical	31.7 (0.9)	38.9 (0.9)	37.7 (0.9)	30.0 (2.2)	35.4 (2.4)	33.0 (2.5)	NS	<.05	NS
Bodily Pain	35.3 (0.8)	41.8 (0.8)	41.4 (0.9)	36.0 (2.0)	41.2 (2.4)	39.5 (2.3)	NS	<.05	NS
General Health	44.0 (0.8)	45.3 (0.8)	43.8 (0.8)	41.1 (1.9)	41.7 (2.0)	40.9 (2.3)	NS	NS	NS
Emotional Well-Being	40.3 (0.9)	46.8 (1.0)	46.7 (1.1)	41.4 (2.2)	46.7 (2.5)	46.0 (2.4)	NS	<.05	NS
Role Limitation—Emotional	36.5 (1.1)	42.1 (1.2)	39.4 (1.2)	34.8 (2.7)	38.4 (3.0)	33.9 (3.1)	NS	NS	NS
Social Functioning	36.3 (0.9)	42.9 (0.9)	41.4 (1.0)	37.0 (2.3)	40.5 (2.6)	38.3 (2.6)	NS	NS	NS
Energy/Fatigue	40.8 (0.8)	46.7 (0.9)	45.5 (1.0)	41.1 (2.1)	45.8 (2.4)	44.5 (2.2)	NS	NS	NS
Physical Component Score	36.2 (0.8)	42.1 (0.8)	40.9 (0.8)	34.9 (1.8)	38.5 (2.0)	36.4 (2.0)	NS	<.05	NS
Mental Component Score	39.7 (0.8)	45.6 (0.8)	44.5 (0.9)	39.7 (1.9)	43.5 (2.2)	41.8 (2.2)	NS	NS	NS

mJOA, modified Japanese Orthopedic Association; NS, not significant; NDI, Neck Disability Index; SF-36v2, version 2 of 36-Item Short Form Health Survey.

There were 78 treatment-related complications reported among the 52 subjects. The overall rate of any complication was 18.7 per 100 subjects (Table 5). The complication rate in diabetic patients was lower than that in nondiabetic patients (11.9% and 19.9%, respectively; p>.05).

Discussion

Our study involves the largest series of patients in the evaluation of the impact of diabetes on severity of CSM and the outcomes of decompressive surgery for CSM. Furthermore, our study is the only study that collected data prospectively and that contains patient-reported functional and quality-of-life outcomes. Patients with diabetes had more significant neurologic impairment at presentation as measured by Nurick grade. Patients with and without diabetes did not differ in preoperative mJOA, NDI score, and SF-36v2. We also found no association between diabetes and outcomes of decompressive surgery, except for the SF-36v2 dimension of Physical Functioning. The improvement in neurologic outcomes as measured by Nurick grade and mJOA scores was similar in patients with and without diabetes. Also, the improvement in patient-reported functional outcomes measured by NDI was similar in subjects with and without diabetes.

Few studies have reported an association between diabetes and surgical outcomes. Kawaguchi et al. [7] performed a retrospective review and compared outcomes in 18 diabetic and 34 nondiabetic patients undergoing cervical laminoplasty. There were no differences between the diabetic and nondiabetic patients in JOA outcome scores, but the sensory recovery in lower extremities was poorer in diabetic patients. Choi et al. [6] retrospectively analyzed

Table 4
Changes in outcome parameters between diabetic and nondiabetic patients receiving decompression surgery for cervical spondylotic myelopathy adjusted for baseline covariates

	Control			Diabetes					
Variable	Baseline	12 mo	24 mo	Baseline	12 mo	24 mo	Diabetes	Time	Time×diabetes
mJOA	12.9 (0.1)	15.7 (0.2)	16.0 (0.2)	12.7 (0.4)	15.8 (0.4)	16.4 (0.4)	NS	<.001	NS
Nurick	4.1 (0.1)	2.5 (0.1)	2.5 (0.1)	4.2 (0.3)	2.5 (0.3)	2.3 (0.3)	NS	<.001	NS
NDI	42.1 (1.3)	30.7 (1.4)	30.8 (1.4)	41.5 (4.3)	31.1 (4.7)	33.1 (4.8)	NS	.003	NS
SF-36v2									
Physical Functioning	32.0 (0.8)	38.7 (0.8)	37.4 (0.8)	35.3 (2.4)	38.0 (2.5)	35.8 (2.5)	NS	NS	<.05
Role Limitation—Physical	31.5 (0.8)	38.7 (0.8)	37.4 (0.8)	31.5 (2.3)	36.8 (2.6)	34.5 (2.6)	NS	<.05	NS
Bodily Pain	35.1 (0.6)	41.7 (0.6)	41.2 (0.8)	37.6 (1.8)	42.8 (2.2)	41.1 (2.1)	NS	<.05	NS
General Health	43.3 (0.6)	44.7 (0.6)	43.0 (0.7)	45.0 (1.7)	45.5 (1.9)	44.8 (2.3)	NS	NS	NS
Emotional Well-Being	40.3 (0.8)	46.7 (0.8)	46.6 (1.0)	41.5 (1.8)	46.9 (2.3)	46.1 (2.1)	NS	<.05	NS
Role Limitation—Emotional	36.2 (0.8)	41.6 (0.9)	39.2 (0.9)	36.5 (1.9)	40.1 (2.3)	35.6 (2.4)	NS	NS	NS
Social Functioning	35.9 (0.7)	42.4 (0.7)	40.9 (0.9)	40.1 (2.1)	43.6 (2.6)	41.4 (2.4)	NS	NS	NS
Energy/Fatigue	40.6 (0.6)	46.5 (0.7)	45.4 (0.8)	42.1 (1.5)	46.7 (2.0)	45.5 (1.8)	NS	NS	NS
Physical Component Score	35.6 (0.6)	41.5 (0.6)	40.3 (0.6)	38.6 (1.8)	42.2 (2.0)	40.1 (2.0)	NS	<.05	NS
Mental Component Score	39.3 (0.63)	45.2 (0.6)	44.1 (0.7)	42.1 (1.9)	46.0 (2.2)	44.2 (2.1)	NS	NS	NS

mJOA, modified Japanese Orthopedic Association; NS, not significant; NDI, Neck Disability Index; SF-36v2, version 2 of 36-Item Short Form Health Survey.

Table 5
Treatment complications in patients with and without diabetes

	Diabetes					
	No (N=236)		Yes (N=42)		Total (N=278)	
Complications	N	%	N	%	N	%
Altered mental status	2	0.8	0	0.0	2	0.7
C5 radiculopathy	5	2.1	0	0.0	5	1.8
Cardiopulmonary event	7	3.0	0	0.0	7	2.5
Deep infection	1	0.4	0	0.0	1	0.4
Durotomy	3	1.3	0	0.0	3	1.1
Dysphagia	8	3.4	1	2.4	9	3.2
Dysphagia (revision surgery)	1	0.4	0	0.0	1	0.4
Dysphonia	1	0.4	0	0.0	1	0.4
Epidural/wound hematoma	1	0.4	1	2.4	2	0.7
Instrumentation failure (no revision surgery)	1	0.4	0	0.0	1	0.4
Instrumentation malposition/migration	3	1.3	0	0.0	3	1.1
Instrumentation/graft migration (no revision surgery)	1	0.4	1	2.4	2	0.7
Miscellaneous	9	3.8	0	0.0	9	3.2
New neurologic deficit (other)	1	0.4	0	0.0	1	0.4
New radiculopathy (not C5)	2	0.8	1	2.4	3	1.1
Pneumonia	1	0.4	0	0.0	1	0.4
Postoperative deformity (kyphosis, no revision surgery)	0	0.0	1	2.4	1	0.4
Postoperative deformity (kyphosis, revision surgery)	1	0.4	0	0.0	1	0.4
Pseudoarthrosis (no revision surgery)	2	0.8	0	0.0	2	0.7
Pseudoarthrosis (revision surgery)	3	1.3	0	0.0	3	1.1
Renal complication	1	0.4	0	0.0	1	0.4
Reoperation not otherwise specified	1	0.4	0	0.0	1	0.4
Stroke	1	0.4	0	0.0	1	0.4
Superficial infection	6	2.5	1	2.4	7	2.5
Superficial infection (from a revision surgery for pseudoarthrosis)	1	0.4	0	0.0	1	0.4
Symptomatic adjacent level disease (no revision surgery)	1	0.4	0	0.0	1	0.4
Symptomatic adjacent segment disease (revision surgery)	1	0.4	0	0.0	1	0.4
Thromboembolism	1	0.4	0	0.0	1	0.4
Worsened axial neck pain	2	0.8	0	0.0	2	0.7
Worsening of myelopathy	3	1.3	0	0.0	3	1.1
Wound hematoma	1	0.4	0	0.0	1	0.4
Total complications	72		6		78	
Subjects with one or more complications	47	19.9	5	11.9	52	18.7

predictors of outcomes in 47 patients undergoing anterior corpectomy and fusion for ossification of the posterior longitudinal ligament. The patients were classified as those who improved their Nurick grade (N=33) and those who failed to improve their Nurick grade (N=14). In a multivariate analysis, diabetes was found to be a single risk factor for poor outcome. However, there were only six subjects with diabetes in the analyzed sample. Kim et al. [5] retrospectively reviewed outcomes of expansive cervical laminoplasty for the treatment of cervical myelopathy in 31 diabetic and 56 nondiabetic patients. The patients were categorized as success or failure based on the recovery rate in JOA. A recovery rate of 50% or more was considered success. Diabetes was significantly associated with failure in recovery rate in multivariate logistic model.

Our results contradict those of Kim et al. [5]. We found no association between diabetes and the mJOA outcomes, whereas Kim et al. found a significant association between diabetes and decreased JOA recovery rate. Although the diabetic population was similar in the two studies, the study by Kim et al. was retrospective in nature, selected patients based on the availability of the follow-up information, and used few adjustors in the analysis, likely because of limited availability of the retrospective data. Furthermore, despite the similarity in the name, the mJOA and JOA are different instruments, and the use of success and failure based on recovery rate in that study differs from our use of absolute improvement in mJOA, as absolute improvement is a more sensitive approach. Yagi et al. [3] investigated signal intensity changes of intramedullary spinal cord on magnetic resonance imaging in patients undergoing surgery for CSM and found that diabetes was not a prognostic factor for signal change. Finally, Dokai et al. [8] retrospectively reviewed outcomes in 13 diabetic and 65 nondiabetic patients. They found no difference in JOA recovery between the groups but suggested poorer recovery of motor and sensory scores in the lower extremities in patients with diabetes.

The extent of improvement for patients with diabetes in our study was similar to the extent of improvement for patients without diabetes on all metrics except the SF-36v2 Physical Functioning dimension. Physical Functioning improved in nondiabetic patients but not in diabetic patients.

Unlike NDI, Physical Functioning measures overall function and is not specific for cervical spine conditions. It is possible that the Physical Functioning dimension is not sensitive enough to capture neck-related functional gains in the presence of systematic disease such as diabetes.

The benefits of surgery should be balanced against the potential for complications. Diabetes potentially increases the risk of complications, in particular postsurgical infections. The overall risk of any treatment-related complications in our study was 19 per 100. There were no significant differences between the diabetic and nondiabetic patients in the rate of treatment-related complications, including infections. In fact, the complication rate was lower in diabetic than in nondiabetic patients.

The key limitation of our study is that it included mostly well-controlled milder cases of diabetes and few moderately severe cases. Severe cases with end-organ damage were not represented in our sample; therefore, our results should not be generalized to this patient population. Furthermore, postoperative rehabilitation was not prescribed by the protocol. It is unlikely that rehabilitation protocols differed for diabetic and nondiabetic patients at the treating institutions.

In summary, the results of this large, prospective, multicenter study indicate that patients with diabetes experience significant neurologic, functional, and quality-of-life improvements as a result of surgical intervention at the same level seen in patients without diabetes. The complication rate did not differ significantly between diabetic and nondiabetic patients. These findings suggest that surgery is a safe and effective treatment in patients with CSM and diabetes. Patients with diabetes and compressive cervical myelopathy should be offered surgery if they are deemed an acceptable surgical risk.

Acknowledgments

This study was sponsored by AO Spine North America, Inc., a 501(c) (3) nonprofit corporation.

Author disclosures:

PMA: Stock Ownership related: Z-plasty (D); Consulting: K2M (B), Stryker Spine (C), Integra Spine (B), Medtronic (B), Spinewave (B); Board of Directors: AOSpine North America (C); Grant: AOSpine North America (E, Paid directly to institution). ***MGF:*** Grant: AOSpine North America (D); Support for Travel to Meetings for the Study or Other Purposes: AOSpine North America (B); Royalties: DePuy Spine (D); Consulting: DePuy Spine (B); Fellowship Support: Medtronic (D). ***BK:*** Grant: AO Foundation (F, Paid directly to institution); Support for Travel to Meetings for the Study or Other Purposes: AOSpine (B); Consulting: Lanx (D), Cerepedics (F), Orbimed (B). ***STY:*** Grant: AOSpine North America (E, Paid directly to institution); Support for Travel to Meetings for the Study or Other Purposes: AOSpine North America (A); Royalties: Stryker (None); Stock Ownership: Phygen (D), Meditech Advisors (B); Consulting: Stryker (None), Medtronic (B); Board of Directors: *The Spine Journal* Deputy Editor (None), Korean American Spine Society (None); Grant: AOSpine (D). ***EMM:*** Consulting: Medtronic (A); Speaking/Teaching Arrangement: AOSpine (B); Grants: DePuy Canada (B, Paid directly to institution), Medtronic (B, Paid directly to institution), Synthes (B, Paid directly to institution), Stryker (B, Paid directly to institution), Zimmer (B, Paid directly to institution); Fellowship Support: AOSpine (D, Paid directly to institution). ***ARV:*** Royalties: DePuy (E), Medtronics (H), Stryker Spine (G), Biomet Spine (E), Globus (F), Nuvasive (Unknown), Aesculap (B); Stock Ownership: Replication Medica (15,250 shares), K-2 Medical (165 shares), Paradigm Spine (146,875 shares), Stout Medical (B), Spine Medica (Unknown), Computational Biodynamics (Unknown), Progressive Spinal Technologies (Unknown), Spinology (28,750 shares), Orthovita (D), Vertiflex (30,000 shares), Small Bone Innovations (30,000 shares), Disc Motion Technology (D), NeuCore (22,000 shares), Cross Current (125,000 shares), Syndicom (2,750 shares), In Vivo (Unknown), Flagship Surgical (D), Advanced Spinal Intellectual Properties (F), Cytonics (Unknown), Bonovo Orthopedics (100,000 shares), Electrolux (D), Gamma Spine (15% of entity), Location Based Intelligence (20% of entity), FlowPharma (Unknown), RIS (less than 5,000 options), Rothman Institute and Related Properties (partner); Consulting: Gerson Lehrman Group (B), Guidepoint Global (B), Medacorp (B), Benvenue Medical (A); Grants: Stryker Spine (E, Paid directly to institution), Cerapedics (Unknown). ***DSB:*** Royalties: Amedica (E), DePuy Synthes (H), Medtronic (C); Stock Ownership: Amedica (<0.1%); Private Investments: Pioneer (<0.1%), Vertiflex (<0.1%); Consulting: DePuy Synthes (B); Board of Directors: CSRS (None), FOSA (None); Fellowship Support: AOSpine (E, Paid directly to institution). ***CIS:*** Grant: AO (B, Paid directly to institution); Royalties: Medtronic (F, Paid to author/institution); Consulting: DePuy (B), Nuvasive (C), Biomet (C), Globus (C); Board of Directors: AANS (None), SRS (None), ABNS (None); Endowments: Harrison Distinguished Professorship (unknown, Paid directly to institution); Grants: NIH (unknown, Paid directly to institution), Department of Defense (unknown, Paid directly to institution), AO (unknown, Paid directly to institution); Fellowship Support: NREF (unknown, Paid directly to institution). ***JSS:*** Consulting: Biomet (C), Medtronic (A), DePuy (A), Globus (A); Honorarium: Biomet (C), Medtronic (A), DePuy (A), Globus (A); Research support: DePuy (B). ***EJW:*** Physician-Owned Distributorship: Paradigm Medical Solutions (15%); Stock Ownership: Medtronic (4,500 shares); Speaking/Teaching Arrangements: DePuy Spine (B); Scientific Advisory Board/Other Office: In Vivo Therapeutics (500,000 stock options). ***RJB:*** Consulting: Spine Art (B), Custom Spine (B), Medacorp (B),

Gerson Lehrman Group (B). ***JRC:*** Consulting: Synthes USA (D); Speaking/Teaching Arrangements: AOSpine (B), Synthes (B); Board of Directors: AOSpine North America (C), AOSpine Foundation (B); Endowments: Hansjoerg Wyss Foundation (I, Paid directly to institution); Research Support: Medtronic (E, Paid directly to institution), Alseres Pharmaceuticals (C); Fellowship Support: AOSpine North America (E, Paid directly to institution), OREF (E, Paid directly to institution). ***MEJ:*** Physician-Owned Distributorship: Musculoskeletal Surgery Center (E); Consulting: Synthes Spine (D); Speaking/Teaching Arrangements: Synthes Spine (D). ***CMB:*** Royalties: LWW, Informa (A); Fellowship Support: OREF (unknown, Paid directly to institution); Other Relationships: Study Design Team, HCRI (B), Intrinsic Therapeutics, DSMB (B). ***RCS:*** Royalties: Medtronic (I); Stock Ownership: Biomet (Unknown); Board of Directors: Cervical Spine Research Society (None). ***MBD:*** Fees for Participation in Review Activities: SpineNet (C, Paid directly to institution); Royalties: Mayo Medical Ventures/Medtronic (F, Paid to author/institution); Consulting: Mayo Medical Ventures/Medtronic (unknown, Paid directly to institution); Speaking/Teaching Arrangements: AO Foundation: (B); Trips/Travel: AAOS, AO Foundation, AANS (B); Scientific Advisory Board: Broadwater Association (B, Paid directly to institution); Research Support: AO Foundation SpineNet (E); Fellowship Support: AO Foundation (F, Paid directly to institution). ***ZLG:*** Grant: AO Spine (E, Paid directly to institution); Support for Travel: AO Spine (variable/unknown); Stock Ownership: US Spine (C), Spinal Kinetics (C); Speaking/Travel Arrangements: AANS (None, Paid directly to institution), CNS (None, Paid directly to institution), Spine Section (None, Paid directly to institution), AO North America (None, Paid directly to institution); Trips/Travel: Visiting Professor (A, Paid directly to institution); Board of Directors: *JNS Spine* (None), *The Spine Journal* (None), *Journal of Spinal Disorders* (None), *European Spine Journal* (None), *Nature Review World Neurosurgery* (None), *Journal of Surgical Oncology* (None), *US Spine* (None); Scientific Advisory Board: NREF (None, Paid directly to institution); Research Support: AO Spine (E), NREF (E); Grant: DePuy (E); Fellowship Support: AO Spine (E, Paid directly to institution), NREF (E, Paid directly to institution).

The disclosure key can be found on the Table of Contents and at www.TheSpineJournalOnline.com.

References

[1] Nurick S. The natural history and the results of surgical treatment of the spinal cord disorder associated with cervical spondylosis. Brain 1972;95:101–8.

[2] Young WF. Cervical spondylotic myelopathy: a common cause of spinal cord dysfunction in older persons. Am Fam Physician 2000;62:1064–70. 1073.

[3] Yagi M, Ninomiya K, Kihara M, Horiuchi Y. Long-term surgical outcome and risk factors in patients with cervical myelopathy and a change in signal intensity of intramedullary spinal cord on magnetic resonance imaging. J Neurosurg Spine 2010;12:59–65.

[4] Matz PG, Anderson PA, Groff MW, et al. Cervical laminoplasty for the treatment of cervical degenerative myelopathy. J Neurosurg Spine 2009;11:157–69.

[5] Kim HJ, Moon SH, Kim HS, et al. Diabetes and smoking as prognostic factors after cervical laminoplasty. J Bone Joint Surg Br 2008;90:1468–72.

[6] Choi S, Lee SH, Lee JY, et al. Factors affecting prognosis of patients who underwent corpectomy and fusion for treatment of cervical ossification of the posterior longitudinal ligament: analysis of 47 patients. J Spinal Disord Tech 2005;18:309–14.

[7] Kawaguchi Y, Matsui H, Ishihara H, et al. Surgical outcome of cervical expansive laminoplasty in patients with diabetes mellitus. Spine 2000;25:551–5.

[8] Dokai T, Nagashima H, Nanjo Y, et al. Surgical outcomes and prognostic factors of cervical spondylotic myelopathy in diabetic patients. Arch Orthop Trauma Surg 2012;132:577–82.

[9] Benzel EC, Lancon J, Kesterson L, Hadden T. Cervical laminectomy and dentate ligament section for cervical spondylotic myelopathy. J Spinal Disord 1991;4:286–95.

[10] Nurick S. The pathogenesis of the spinal cord disorder associated with cervical spondylosis. Brain 1972;95:87–100.

[11] Vernon H, Mior S. The Neck Disability Index: a study of reliability and validity. J Manipulative Physiol Ther 1991;14:409–15.

[12] Ware JE Jr, Sherbourne CD. The MOS 36-item short-form health survey (SF-36). I. Conceptual framework and item selection. Med Care 1992;30:473–83.

[13] Rubin DB. Multiple imputation for nonresponse in surveys. New York, NY: John Wiley & Sons, Inc., 1987.

[14] Shafer JL. Analysis of incomplete multivariate data. In: Cox DR, Isham V, Keiding N, et al, eds. Monographs on statistics and applied probability. London, UK: Chapman & Hall/CRC, 1997.

[15] Barnard J, Meng XL. Applications of multiple imputation in medical studies: from AIDS to NHANES. Stat Methods Med Res 1999;8:17–36.